

§ 158.2110 Microbial pesticides data requirements.

(a) *For all microbial pesticides.* (1) The following § 158.2120 through § 158.2150 identify the data requirements that are required to support registration of microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) Each data table includes “use patterns” under which the individual data are required, with variations including all use patterns, food and nonfood uses for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(3) The categories for each data requirement are “R,” which stands for required, and “CR” which stands for conditionally required. If a bracket appears around the “R” or “CR,” the data are required for both the registration and experimental use permit requests. Generally, “R” indicates that the data are more likely required than for those data requirements with “CR.” However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(4) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (*i.e.*, TGAI, EP) indicate that data may be required on the TGAI or EP or both depending on the conditions set forth in the test note. Data requirements which list two test substances (*i.e.*, TGAI and EP) indicate that both are required to be tested. Data requirements that list only MP as the test substance apply to products containing

solely the technical grade of the active ingredient and manufacturing-use products to which other ingredients have been intentionally added. Data requirements listing the EP as the test substance apply to any EP with an ingredient in the end-use formulation other than the active ingredient that is expected to enhance the toxicity of the product.

(b) *Additional data requirements for genetically modified microbial pesticides.* Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the “new” traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2120 Microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section.

(b) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; All = All of the above.

(c) *Table.* The table in this paragraph shows the data requirements for microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Test guideline No.	Data requirement	All use patterns	Test substance		Test notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product identity	R	MP	EP.	1
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP.	
885.1250	Deposition of a sample in a nationally recognized culture collection.	R	TGAI	TGAI	
885.1300	Discussion of formation of unintentional ingredients.	R	TGAI and MP	TGAI and EP.	
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2
885.1500	Certification of limits	R	MP	EP.	
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI.	
830.6303	Physical state	R	TGAI	TGAI.	
830.6304	Odor	R	TGAI	TGAI.	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions.	R	TGAI	TGAI.	
830.6317	Storage stability	R	TGAI and MP	TGAI and EP.	3
830.6319	Miscibility	R	MP	EP	
830.6320	Corrosion characteristics	R	MP	EP	4
830.7000	pH	R	TGAI	TGAI.	5
830.7100	Viscosity	R	MP	EP	
830.7300	Density/relative density/bulk density (specific gravity).	R	TGAI	TGAI	

(d) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required for each isolate of a microbial pesticide. Isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated registration(s).

2. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

3. Only required for emulsifiable liquid forms of microbial pesticides.

4. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

5. Only required for liquid forms of microbial pesticides.

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§ 158.2130 Microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in paragraph (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticides residue. The test notes are shown in paragraph (d) of this section.